IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF DIONYSIOS K. VERONIKIS, M.D.

Plaintiffs attempt to transform the methodologically flawed opinions Ethicon challenges here into those based on sound scientific methodology simply because Dr. Veronikis may be qualified to give expert testimony. Ethicon did not base its *Daubert* challenge on qualifications. Consequently, Plaintiff's recital of Dr. Veronikis's qualifications (Pls.' Resp. (Dkt. 2284) at 1-2) is both unnecessary and immaterial. No matter how qualified Dr. Veronikis may be to give opinions in this case, "he must still base his opinions on a reliable, scientific method." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 680 (S.D.W. Va. 2014).

Some of the opinions challenged here are not based on a reliable, scientific method. Others are irrelevant, unhelpful, or misleading under Rules 702, 703, and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Plaintiffs' arguments in opposition do not cure these deficiencies. Specifically, Plaintiffs:

- fail to recognize that Dr. Veronikis's reliance on internal company documents is not for the permissible purpose of providing bases for his warnings opinions, but to impermissibly show what Ethicon "knew";
- fail to acknowledge that even though Dr. Veronikis testified that he has seen evidence of degradation, that experience is not a reliable basis for his opinion that degradation leads to adverse clinical outcomes because

  - his opinion that degradation causes clinical consequences is only backed by his "interpretation" of internal company documents; and
  - his opinion that degradation occurs does not "fit" the general causation issues in this case, which requires evidence that degradation causes the types of injuries Plaintiffs have allegedly sustained;

- are unable to controvert case law from across the country, including the Fourth Circuit, holding that evidence of alternative surgical techniques is irrelevant to claims for design defect;
- ignore the fact that Dr. Veronikis's continued use of polypropylene mesh slings to treat stress urinary incontinence renders his opinion that "all polypropylene slings are unsafe" unreliable;
- fail to recognize that Ethicon's Pronova product cannot be considered a feasible alternative design because it is not legally available for use in prolapse repair;
- continue to assert that Dr. Veronikis may offer opinions regarding the "dangerousness" of the TVT or Gynemesh PS products despite recognizing that an expert is prohibited from offering legal conclusions;
- fail to recognize that Dr. Veronikis should be precluded from offering the corporate-motive opinions expressed in his Gynemesh PS Report, despite acknowledging that this Court disallows expert opinions that go to Ethicon's motives or intention.

Accordingly, as explained more fully below, Ethicon respectfully asks this Court to exclude the opinions of Dr. Veronikis as set forth in its Memorandum. *See* Defs.' Mem. (Dkt. 2271).

ARGUMENTS AND AUTHORITIES

I. Dr. Veronikis's interpretation of Ethicon's internal documents is offered to show what Ethicon knew, not to explain the basis for his inadequate-warning opinion.

Ethicon acknowledges that an expert "may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions," *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014), but that is not the reason why Dr. Veronikis relies on Ethicon's internal documents here. Rather, Plaintiffs themselves concede that Dr. Veronikis will use Ethicon's

company documents as the basis for his testimony about: 1) "what information was available to Defendants regarding the safety and efficacy of the TVT and Gynemesh PS"; 2) "[w]hether Defendants were aware of other risks, or information that that the TVT or Gynemesh PS could increase the frequency, severity, or duration of known risks"; and 3) what information "was known by—or at least knowable by or available to—Defendants about the products in question as reflected in Defendants' own internal documents." Pls.' Resp. (Dkt. 2284) at 3.

Plaintiffs try to exempt Dr. Veronikis's "corporate knowledge" opinion by claiming it does not go to Ethicon's "motives or intent" or otherwise speak to "corporate conduct or ethics." *Id.* But corporate motives, intent, or ethics are not the only bases of improper testimony by an expert relying on internal company documents. As this Court has repeatedly held, an expert is also prohibited from testifying about what a company "knows" or "knew" based on that expert's review of company records. *See* Defs.' Mem. (Dkt. 2271) at 4. The jury is capable of reading and interpreting company documents without an expert witness to explain what those documents mean. *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *10 (S.D.W. Va. July 8, 2014). Dr. Veronikis should be precluded from interpreting Ethicon company documents and testifying to what he claims Ethicon "knew."

II. The fact that Dr. Veronikis claims to have witnessed degradation in TVT explants is not a reliable basis for his opinion that degradation causes clinical problems.

Plaintiffs' assertion that Dr. Veronikis has "personally observed" TVT mesh degradation, fraying, and particle loss, Pls.' Resp. (Dkt. 2284) at 6, does not change the fact that all that undergirds his degradation opinion is an impermissible narrative review of Ethicon's internal company documents. *See* Defs.' Mem. (Dkt. 2271) at 5-6. Dr. Veronikis did not testify that he had personally observed adverse clinical consequences that were *caused* by TVT degradation, and conceded during his deposition that he has "not yet" seen any "published scientific literature

where fraying and the TVT® mesh falling apart was recognized to be a problem." *Id.* at 5 (citing Veronikis 4/30/16 Dep. Tr. 72:20-73:7). In their Opposition, Plaintiffs cite several parts of Dr. Veronikis's deposition transcript in which he discussed degradation or fraying, and yet not one of those references connects this alleged fraying to clinical problems. *See* Pls.' Resp. (Dkt. 2284) at 6. In short, Dr. Veronikis may testify that he has *seen* degradation occur, but there is no reliable basis for him to opine that it causes clinical problems.

Of course, as a purported general-causation expert, Dr. Veronikis's inability to testify that degradation *causes* adverse clinical outcomes is problematic. Without testimony linking degradation with clinical problems, Dr. Veronikis simply cannot provide the necessary link between his opinion that mesh degrades and his opinions that degradation causes clinical sequelae. This gap between the data on which Dr. Veronikis relies and the opinions he offers in his report render his degradation opinions inadmissible. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997) ("Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."). The Court should therefore exclude them under *Daubert*.

III. This Court's preemption analysis has nothing to do with whether Dr. Veronikis's surgical technique opinion can support a claim for design defect; Plaintiffs' argument ignores uncontroverted Fourth Circuit precedent.

It is "well established that a medical device manufacturer is not responsible for the practice of medicine." *Sons v. Medtronic, Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013). For "physician-prescribed drugs and medical devices, the physician 'is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment.'" *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163 (4th Cir. 1999).

Dr. Veronikis's criticism of the surgical procedure recommended by Ethicon for TVT implantation does not demonstrate a design defect in the TVT mesh product, as Plaintiffs claim.

Pls.' Resp. (Dkt. 2284) at 8. In *Talley*, the Fourth Circuit clarified that such assertions "questioned the medical judgment of doctors," and might be relevant in a malpractice suit against the doctor, but not in a suit against the device manufacturer. *Talley*, 179 F.3d at 162. Surgical alternatives "[do] not indicate any design flaw." *Id.* Indeed, courts have rejected Plaintiffs' surgical-technique design-defect argument (*see* Defs.' Mem. at (Dkt. 2271) at 6-7), and Plaintiffs cite no case law that supports their erroneous argument.

Instead, Plaintiffs claim that Ethicon's argument is "self-contradictory" and conflicts with *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748 (S.D.W. Va. 2014). Not so. *Lewis* addressed *preemption*—i.e., whether the plaintiff's design-defect claims were preempted if the Prolene sutures that were part of the TVT mesh device went through the FDA's premarket approval process. Surgical technique was not discussed, was not at issue, and consequently had no bearing on the *Lewis* court's analysis or ruling. There is no conflict.

Ethicon's argument here does not "contradict" its argument in *Lewis*. Instead, Ethicon asks this Court to rule consistent with the Fourth Circuit and courts across the country that, while Dr. Veronikis's surgical-technique opinions may be relevant to other claims, they are not relevant to design-defect claims in general, and cannot support Plaintiffs' contention that TVT is defectively designed. *See Talley*, 179 F.3d at 162 (rejecting plaintiff's theory that defendant's spinal-fixation device was defective because there were alternative spinal-fusion procedures available that did not use spinal-fixation devices); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013).

Dr. Moore's surgical-technique design-defect opinion runs counter to established and uncontroverted Fourth Circuit precedent, and therefore is irrelevant to a claim for design defect. *See Daubert*, 509 U.S. at 591-92 (explaining that an expert's opinion must "fit" the relevant inquiry, and that scientific validity for one purpose is not necessarily scientific validity for other purposes).

IV. Plaintiffs concede that Dr. Veronikis may not opine that "all polypropylene slings are unsafe."

Plaintiffs brush aside Dr. Veronikis's testimony that he believes *all* polypropylene slings to be unsafe, regardless of use, as nothing more than a "red herring," Pls.' Resp. (Dkt. 2284) at 11 n.6, and ask this Court to deny Ethicon's request to exclude that opinion as moot because it did not appear in his expert report and he will not offer it at trial. But Dr. Veronikis offered the opinion nevertheless and he should be precluded from offering it at trial.

Moreover, the fact that Dr. Veronikis holds this opinion, despite continuing to use polypropylene slings as part of his private practice for treating patient with stress urinary incontinence, calls into question the reliability of his methodology. Even if Dr. Veronikis does not testify to this opinion at trial, the fact remains that his actual practice cannot be squared with his litigation-driven opinions. This is not the intellectual rigor that *Daubert* requires of an expert witness. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (instructing that an expert must employ in the courtroom "the same level of intellectual rigor that characterizes the practice of an expert" in the expert's field).

V. An alternative design that is not commercially available is not a *feasible* alternative design to support a design-defect claim.

Plaintiffs' sole argument against excluding Dr. Veronikis's opinions regarding Pronova misses the point. Even assuming that Dr. Veronikis *could* rely on internal Ethicon company documents to identify Pronova as a safer alternative for prolapse repair, as Plaintiffs suggests,

Pls.' Resp. (Dkt. 2284) at 11, Plaintiffs ignore Dr. Veronikis's own concession that Pronova is not available for prolapse repair. Defs.' Mem. (Dkt. 2271) at 10 (citing Veronikis 4/30/16 Dep. Tr. 237:13-20). It is undisputed that a prescription medical device cannot be legally sold in the United States without either FDA approval or clearance. Before that time, an alternative prescription product is simply not a "feasible" alternative because it is not legally available.

VI. Plaintiffs concede Dr. Veronikis cannot offer legal conclusions, but then claim he can.

Despite conceding that an expert cannot offer legal conclusions, Plaintiffs nonetheless claim that Dr. Veronikis can testify regarding the "dangerousness" of the TVT or Gynemesh PS products and that Ethicon failed to adequately warn or instruct about these products. Pls.' Resp. (Dkt. 2284) at 13. But these *are* legal conclusions that are within the province of the jury, not Dr. Veronikis. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013) (distinguishing between an expert's permissible opinion under Rule 704 and when that expert instead offers an impermissible legal conclusion); *see also Eghnayem*, 57 F. Supp. 3d at 691.

VII. Plaintiffs concede that Dr. Veronikis may not opine on Ethicon's corporate motives.

Finally, Plaintiffs acknowledge that this Court has disallowed "expert opinions that go to Defendants' 'state of mind, knowledge, motives, or intention," and aver that they "do not intend to have Dr. Veronikis offer any such opinions at trial." Pls.' Resp. (Dkt. 2284) at 13 (citing *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *13 (S.D.W. Va. Feb. 7, 2015)). Yet in his Gynemesh PS report, Dr. Veronikis identified opinions that Ethicon's IFU was "intentionally misleading" and "needlessly endangering" its patients, and that "Ethicon's documents reflect an intent to 'differentiate'" study results that were not supportive of Prolift's "clinical safety." Defs.' Mem. (Dkt. 2271) at 12. Rather than risk eliciting this impermissible

testimony at trial, this Court should enter an order precluding any such corporate motive opinions.

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Dionysios K. Veronikis, M.D., and limit his opinions for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on June 15, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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